[Insert Site Name]

CANDELA

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URGENT: Medical Device Field Safety Notice

GentleCool Pro Cryogen Canister

September 13th, 2019

Dear Valued Customer

This letter is to inform you that Candela Medical is conducting a Field Safety Corrective Action on specific lots, detailed on Page 2, of the GentleCool Pro Cryogen Canister. Candela has received reports that the neck bushing (or top) may become partially or completely separated from the canister during use.

Risk to Health:

The canister compromise is characterized by the neck bushing (or top) of the canister becoming disconnected from the body of the canister, causing rapid depressurization. This event can injure the patient/operator by A) uncontrolled cryogen gas spray and B) propelling the gas canister away from the system in an uncontrolled manner with significant velocity.

Actions to Be Taken by the Customer/User:

To safely and efficiently implement this Field Safety Corrective Action, we are asking that you please take the following actions:

1. Immediately examine your inventory and quarantine the identified lots of the GentleCool Pro Cryogen Canister.
2. Immediately discontinue use and distribution of the identified lots of the GentleCool Pro Cryogen Canister.
3. Please complete and return the enclosed "Urgent FSN Acknowledgement Form- GentleCool Pro Canister". The completed form must be scanned and emailed to *cryogen.Insertcountryname @candelamedical.com* within 24 hours.
4. If you may have further distributed this product, please identify those locations and notify them at once of this product Field Safety Corrective Action. Your communication should include a copy of this Field Safety Notice letter.
5. Please contact Candela Customer Service at *800-733-8550 ext. 0* to make arrangements for replacement of your affected inventory.
6. Information regarding retrieval of your affected inventory will be forthcoming from Candela Medical.

Affected Product and Lot Information:

Product(s)	Product Number(s)	Lot Number
Canister HFC-134a /lOOOg, ALUM	1600-00-0218	1904CC1598 1905CC0007
Canister HFC-134a /lOOOg, ALUM, 15 pack	1600-00-0219	1905CC0178 1905CC0217
Canister HFC-134a / 980g, ALUM	1600-00-0223	1906CC0196 1906CC0172
Canister HFC-134a /980g, ALUM, 15 pack	1600-00-0224	1907CC0008 1908CC0025

We have further determined that the issue occurs only when the canisters are used in Candela legacy devices that utilize "screw-in" or "threaded interface" type DCD modules. These legacy devices are shown in the table below:

Product(s)	Product Number(s)
Gentle Devices	
GentleLase	9914-XX-2103
GentleLase Plus	9914-XX-2130
GentleLase (MGL)	9914-XX-0880
GentleYag (VPYAG)	9914-XX-0950
Vbeam Devices	
Vbeam	9914-XX-0720
Diode Devices	
Smoothbeam	9914-XX-0820
Cbeam	9914-XX-0710

This Field Safety Corrective Action is being made with the knowledge of the Competent Authorities within your country.

We apologize for any inconvenience that this Field Safety Corrective Action creates for both you and your clients. However, we want to make every effort to ensure we are providing our customers with the ability to have the safest device operation possible. Thanks in advance for your assistance.

If you have any questions, please do not hesitate to call our Customer Service team at *800-733-8550 ext.* 0, M-F 8:30am
-8 pm EST, or reach them via email at cryogen.insertcountryname@candelamedical.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to your Candela representative.

Sincerely,

Sharon Timberlake
Vice President, Global Regulatory Affairs